

Attorney Docket No.: PTQ-0028  
Inventors: Van Eyk et al.  
Serial No.: 09/419,901  
Filing Date: October 18, 1999  
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#### REMARKS

Claims 1-7, 15-28, 31, 34, 35 and 37-41 are pending in the instant application. Claims 1-7, 15-28, 31, 34, 35 and 37-41 have been rejected. Claims 1, 2, 3, 4, 5, 6, 7, 20, 22, 35 and 37 have been amended. Claim 19 has been canceled. Support for this amendment is provided in claim 19, now canceled, and in the specification at page 14, lines 5-26. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### I. Information Disclosure Statement

It is respectfully pointed out that the listing of references in the specification was not meant by Applicants to serve as the Information Disclosure Statement in the instant application. Applicants submitted Information Disclosure Statements pursuant to 37 C.F.R. 1.56 and in accordance with 37 C.F.R. 1.97-1.98 and inclusive of copies of all references listed therein on April 13, 2000, January 21, 2004 and April 14, 2005.

#### II. Obviousness-type Double Patenting Rejection

Claims 1-7, 15-28, 31, 34-35 and 37-41 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable

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over claims 1-28 of copending Application No. 09/115,589. The Examiner has agreed, however, to hold this rejection in abeyance until one of the applications is allowed. Should an obviousness-type double patenting issue still exist at that time, Applicants will file the appropriate terminal disclaimer.

**III. Rejection of Claims 1, 15 and 16 under 35 U.S.C.**

**102(b)**

Claims 1, 15 and 16 remain rejected under 35 U.S.C. 102(b) as being anticipated by Wicks et al. (WO 94/27156) as the Examiner suggests that the claims read on instances where the chemical adduct is absent. Thus, the Examiner suggests that the only required detection is a myofilament protein modification and that TnI meets this requirement.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants filed a Request for Continued Examination on April 14, 2005 and are amending the claims herein to delete the phrase "or absence" from claim 1. Further Applicants have amended claim 1 to clarify that it is the presence of at least one myofilament protein modification product which is a chemical adduct of a myofilament protein selected from the group consisting of troponin I, troponin T, troponin C,  $\alpha$ -actinin, actin,

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tropomyosin, desmin, myosin light chain 1, myosin light chain 2, and myosin light chain 3 that is an indicator of muscle damage in the subject. Applicants have also amended claim 1 to state that the chemical adduct of the myofilament protein is a post-translational modification of an intact myofilament protein, a post-translational modification of a degradation product of a myofilament protein or a post-translation modification of a protein-protein complex of myofilament proteins. Support for these amendment is provided in the specification at page 14, line 5 through 26.

Nowhere does Wicks teach methods for detecting the claimed chemical adducts nor the relationship of such chemical adducts to muscle damage.

As Wicks does not teach a method for detection of such chemical adducts, this reference cannot anticipate the claims as amended.

Withdrawal of this rejection under 35 U.S.C. 102(b) is therefore respectfully requested.

IV. Rejection of Claims 2-7, 17-28, 31, 33-35 and 37-41 under 35 U.S.C. 103(a)

Claims 2-7, 17-28, 31, 33-35 and 37-41 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Wicks et al. (WO 94/27156) in view of Wicks et al. (U.S.

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Patent 5,834,220) and in further view of Van Eyk et al.  
(U.S. Patent 6,248,549).

Applicants respectfully traverse this rejection.

As discussed in Section III, supra, the claims of the instant application have been amended to require detection of a chemical adduct of the myofilament protein. Further, the myofilament protein has been defined in accordance with claim 19, now canceled; to be selected from the group consisting of troponin I, troponin T, troponin C,  $\alpha$ -actinin, actin, tropomyosin, desmin, myosin light chain 1, myosin light chain 2, and myosin light chain 3.

Nowhere do Wicks (WO 94/27156) or Wicks et al. (U.S. Patent 5,834,220) teach or suggest detection of the presence of such chemical adducts.

Further, teachings of Van Eyk et al. (U.S. Patent 6,248,549) relate to p21-activated kinase proteins, not to a chemical adduct of a myofilament protein selected from the group consisting of troponin I, troponin T, troponin C,  $\alpha$ -actinin, actin, tropomyosin, desmin, myosin light chain 1, myosin light chain 2, and myosin light chain 3. Thus, while Applicants respectfully disagree with the Examiner that Dr. Van Eyk's Declaration is ineffective to overcome this reference, amendments to the claims clearly distinguishing

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the present invention from teachings of U.S. Patent 6,248,549 render moot any requirement for further showing that Dr. Van Eyk made the invention upon which the relevant disclosure in the patent is based.

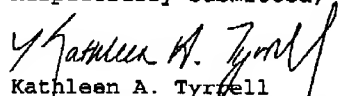
Since the cited combination of references does not teach or suggest all the limitations of the instant claimed invention, it cannot render the instant claimed invention prima facie obvious. MPEP 2143.

Withdrawal of this rejection under 35 U.S.C. 103(a) is therefore respectfully requested.

#### V. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

  
Kathleen A. Tyrrell  
Registration No. 38,350

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Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, New Jersey 08053  
(856) 810-1515